

Colistimethate sodium lyophilized vials

Colistimethate sodium is a prodrug of colistin, which is a mixture of polypeptide antibiotics active against gram-negative bacteria, including *Enterobacter aerogenes*, *Escherichia coli*, *Klebsiella pneumoniae* and especially *Pseudomonas aeruginosa*.

Indication: Used in the treatment of acute or chronic infections due to sensitive strains of gram-negative pathogens. It is particularly indicated when the infection is caused by sensitive strains of *Pseudomonas aeruginosa*.

Application: Administered systemically as intramuscular injections and intravenous injections or infusions.

Product grades	Lyophilized vials
Strength	150 mg colistin base activity*
Compliance	No monograph for colistimethate sodium vials in Ph. Eur. available USP monograph for colistimethate for injection available
Manufacturing site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark
Release site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark
Site registered	EU GMP issued by Danish Medicines Agency US FDA
Regulatory documentation	US dossier RoW** dossier
Batch size	80500 vials
Packaging sizes	1 vial/pack 10 vials/pack 12 vials/pack Possibility for different packaging configuration can be discussed with your Sales Representative
Shelf-life	RoW**: 36 months US: 24 months
Storage conditions	Between 15-25°C (59-77°F) depending on territory

* Equivalent to ~4.5 Million International Units
**Rest of the World